201-14896

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12/15/2003 03:42 PM

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Subject: Environmental Defense comments on Primene 81-R Amine (CAS# 68955-53-3)

(Submitted via Internet 12/15/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and JmcLaughlin@rohmhaas.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Primene 81-R Amine (CAS# 68955-53-3).

The test plan and robust summaries on Primene 81-R Amine were submitted by Rohm and Haas Company. The documents are complete, objective and well organized. We agree with the sponsor that available data are sufficient to meet the requirements of the HPV program and that no additional testing is needed. However, we do have a few concerns regarding inconsistencies in the test plan and robust summaries.

Primene 81-R amine is actually comprised of a mixture of aliphatic (C10-14) amines. It is used to enhance the stability and performance of petroleum-based industrial lubricants, as well as in the production of industrial surfactants and solvent-based dyes. It is also used to inhibit sludge formation in fuel and diesel oils. It has irritancy properties and has been shown to cause delayed contact hypersensitivity in workers, so rigorous industrial hygiene practices are needed for worker protection.

Specific comments on the test plan and robust summaries are as follows:

1. The robust summary on page 8 states that Primene 81-R amine is very toxic to aquatic organisms. However, the test plan characterizes aquatic toxicity as moderate. Since the LC 50's are approximately 1 mg/L, Primene is at least moderately toxic. In any event, the available data on aquatic toxicity exceeds HPV requirements by including data on hatchability and fish behavior.

2. The variability of the amine mixture is not well described in the test plan and robust summaries. Information in Sections 1.1-1.4 of the robust summary indicates that over 95% of the mixture is comprised of C10-C14 aliphatic amines. However, no information is provided on the degree of branching or the quantities of possible contaminants such as olefins and formamide. This information needs to be supplied in the robust summaries. Also, if the mixture is variable, the extent and nature of the variability need to be described for studies on separate endpoints.

3 On page 20 of the robust summary, it is stated that Primene 81-R does not

partition well into the atmosphere, while on page 20 it is stated that the substance easily partitions into the atmosphere. Which statement is correct?

4. The acute toxicity and other mammalian toxicity studies demonstrate that Primene 81-R is more toxic when administered via the dermal route than the oral route. Is this because of metabolic, toxicokinetic and/or cell sensitivity mechanisms? We commend the sponsor on conducting the mammalian toxicity studies using multiple routes of administration.

5. Neurotoxicity (ataxia, hyperactivity, tremors, etc.) is the most sensitive response in repeat dose studies regardless of the route of administration. Are there available studies that identify specific neurological lesions that might account for these effects?

Thank you for this opportunity to comment.

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